NATIONAL FISHERIES INSTITUTE

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March 5, 2003

Office of Management and Budget
Office of Information and Regulatory Affairs
New Executive Office Building
725 17th Street, N.W.
Room 10235
Washington, DC 20503

Re: FDA Docket No. 02N-0278, Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness & Response Act of 2002

Dear Sir of Madam:

The National Fisheries Institute (NFI) appreciates the opportunity to offer written comments on the Paperwork Reduction Act (PRA) portion of the proposed regulation to implement the prior notice requirements of the Bioterrorism Act.

The NFI is the nation's leading trade association for the diverse fish and seafood industry of the United States. The NFI represents fishing vessel owners, processors, importers, exporters, distributors, aquaculturalists, seafood retailers and restaurants. NFI is committed to assisting our member companies in providing consumers with safe, wholesome, diverse and sustainable seafood choices.

The NFI is assessing the economic impacts of the proposed regulation as well as studying the feasibility of providing prior notice information in accordance with the requirements proposed by the Food and Drug Administration (FDA). The assessment is not complete, however, we will provide some of our preliminary findings in the context of the PRA. NFI intends to submit substantive comments to FDA on the impacts and feasibility of the proposed prior notice system by the April 4, 2003 deadline. Additional information on the economic impacts of complying with other requirements will be provided to FDA at that time.

NFI believes that the proposed system will add substantial cost to the importation of covered food items. Several factors will increase the costs associated with import entries including training of filers and importers who must work together to understand and conform to the requirements; additional time and, labor to input and submit the requested information; possible software upgrades; and the possibility of devaluation or loss of seafood shipments when entries are held as a result of apparent filing errors associated with prior notice requirements.

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The information that FDA plans to require in a prior notice submission far exceeds the information specified in the Bioterrorism Act. The proliferation of data required (the submission form could be up to five pages of information per line entry) will take much longer and require considerably more resources than currently necessary to make entry with U.S. Customs.

Certain proposed data requirements such as grower and size of seafood will result in multiple prior notice submissions for shipments previously entered with U.S. Customs as a single entry. This will increase both complexity of and labor costs associated with making entry. Other requirements such as time of arrival in port will require greater coverage by filers perhaps approaching twenty-four hours, seven days a week. This will necessitate overtime or additional staffing by brokers and, perhaps importers. Ongoing analysis further suggests it may be problematic to even obtain precise arrival time information in the time constraints proposed. NFI has been informed by customs brokers familiar with seafood imports that the cost of making entry will increase from 50% to 70%. FDA has not included any of these very significant costs in its analysis of the proposed rule's impacts upon businesses.

The complexity of and the current time lines required for the proposed prior notice system could result in devaluation or loss of seafood products. NFI is particularly concerned with perishable fresh seafood imports. The FDA stipulated minimum submission time is noon the day before the shipment arrives. In the fresh fish business the harvest of fish may be occurring the day before the shipment arrives, which will make precise prior entry notification difficult under the proposed system, particularly given the amount of information FDA plans to require.

The greater the amount of advance notice time required, the greater the possibility that the required prior notice information will need revision. NFI believes this will increase the possibility of shipments being held for erroneous data elements. Perishable fish loses quality, therefore, market value very quickly. Delays as little as 24 hours can substantially affect value and marketability.

FDA's calculations of the costs to the fresh fish and seafood industry from shipments refused entry due to inadequate prior notice are understated and flawed. FDA concludes that its proposed prior notice timeframe of noon of the day prior to arrival at port of entry, with one opportunity to amend, is the least costly to industry (Table 17, 68 Fed. Reg. at 5435). Yet, for that option to be the least costly, FDA assumes, without explanation, that under the other options (4 hour prior notice or 8 hour prior notice), filers will only be able to amend a filed notice entered by noon of the previous day, and may not amend if the notice is filed 4 or 8 hours prior to arrival. By eliminating the opportunity to amend a prior notice filed 4 or 8 hours prior to arrival at port, FDA significantly inflates the costs of those proposals and does not offer a true comparison of the costs of each option.

Additionally, FDA has not considered how the current OASIS system, that captures nearly all of the information specified in the Bioterrorism Act could not be modified to accommodate the Act's requirements. Instead, FDA has created a whole new, complex and untested reporting system that duplicates existing information collection and submission burdens.

NFI's analysis of the economic impact to its industry members is still preliminary. NFI intends to submit additional data to FDA by the April 4, 2003 deadline.

The NFI is a member of the National Coalition of Food Importing Associations (NCFIA) which is also submitting comments concerning the Paperwork Reduction Act. NFI wishes to include NCFIA's comments in ours by reference.

NFI thanks OMB and FDA for the opportunity to comment on the PRA portion of FDA's Prior Notice Proposed Rule.

Sincerely,

Robert Collette

Robert Collette
Vice President, Science and Technology
National Fisheries Institute

CC: FDA Dockets Management Branch